Message

From: Ex. 6 Personal Privacy (PP)
Sent: 4/2/2020 8:23:46 PM
To:
CC: Ex. 6 Personal Privacy (PP)
Subject: Fw: MCAN issue - potentially needs elevation to management

Hi Ex. 6 Personal Privacy (PP),

Hope you are doing well. I am forwarding this email to you just in case Ex. 6 Personal Privacy (PP) is not available.

From: Ex. 6 Personal Privacy (PP)
Sent: Thursday, April 2, 2020 4:20 PM
To: Ex. 6 Personal Privacy (PP)
Subject: Fw: MCAN issue - potentially needs elevation to management

Ex. 6 Personal Privacy (PP)

I sent an email to you on the CBI side yesterday about this case. It has become a "hair on fire" case because the submitter appears to be willing to complain to senior mgmt. if we issue an incomplete letter. Please read the email below. I will try calling you.

From: Ex. 6 Personal Privacy (PP)
Sent: Thursday, April 2, 2020 3:26 PM
To: Ex. 6 Personal Privacy (PP)
Subject: FW: MCAN issue - potentially needs elevation to management

Ex. 6 Personal Privacy (PP), could you give Ex. 6 Personal Privacy (PP) a call about this?

From: Ex. 6 Personal Privacy (PP)
Sent: Thursday, April 02, 2020 2:04 PM
To: Ex. 6 Personal Privacy (PP)
Subject: MCAN issue - potentially needs elevation to management

Hi Ex. 6 Personal Privacy (PP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Sincerely,

Ex. 6 Personal Privacy (PP)

From: Ex. 6 Personal Privacy (PP)
Sent: Thursday, April 2, 2020 11:16 AM
To: Ex. 6 Personal Privacy (PP)
Cc: GRIECO, LIANE M <Liane.M.Grieco@dupont.com>
Subject: RE: Update on MCAN

Hi Ex. 6 Personal Privacy (PP)

Would it be possible for EPA to provide a technical basis (e.g., literature citations) to substantiate their position that when an *S. cerevisiae* is crossed with another *S. cerevisiae* (both parents with taxonomic substantiation that is acknowledged by EPA) that the resulting progeny is not S. cerevisiae? We would be happy to provide several literature citations (likely in the thousands) to demonstrate that when two of the same species are mated, the same species results. Therefore, there is a technical position heavily supported by the scientific community that the GPY10145 will be *S. cerevisiae*, and that there is sufficient information provided in the MCAN for EPA to make this determination. Direct information on GPY10145 is therefore not needed in this case, although DuPont is communicating that we have direct evidence on GPY10145 that we working on to provide to EPA. In addition, we have information in the MCAN supporting through phenotypic characterization in Section 5.2.1 that the resulting new microorganisms behave like *S. cerevisiae*.

Would EPA like to have a call with our R&D team to understand how crosses between the same species results in the same species? Otherwise, if EPA moves forward with a decision to consider this submission incomplete, we will contact EPA upper management to discuss this issue as there is sufficient information in the MCAN to make the determination that the recipient strain is *S. cerevisiae*. Please let me know if you have any further concerns or questions.

Best regards,
Alice

Alice Chen, Ph.D.
Senior Manager for North America, Regulatory Affairs and Product Stewardship
DuPont Nutrition and Biosciences

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